REMARKS

Claims 1-5, 54, 56, 58-61, 63-70, 78-79, 82-83 and 104-107 are pending. Claims 54, 64, 65 and 70 have been amended. No new matter is added.

The Office Action has objected to the specification in the description of Figure 2. The specification has been amended in accordance with the Examiner's suggestion. Withdrawal of the objection is requested.

Claims 54, 56, 58-70, 72-76, 78-79, 82-83 and 104-107 have been rejected under 35 U.S.C. 112, second paragraph. The claims have been amended to reference positive numbering of nucleotides in the sequence listing. Withdrawal of the rejection is requested.

Claims 1-5, 54, 56, 58-61, 63-70, 78-79, 82-83 and 104-107 have been rejected under 35 U.S.C. 112, first paragraph. The Office Action states that the term "**comprising**" "uroplakin II (UPII) transcriptional response element encompasses homologs of the human or murine regulatory elements taught in the instant specification that are obtained from alternative sources, and would include any enhancer element that regulates expression of the uroplakin II gene that are not homologous to the provided sequences.

It is stated the TRE might encompass additional transcriptional response elements that are not present in SEQ ID NOs: 1 or 2, and would therefore encompass a "very large number of potential TRE sequences". The Office Action therefore concludes that "applicants were not in possession of the claimed invention.

Applicants respectfully submit that the present claims meet the requirements of 35 U.S.C. 112, first paragraph, and that in no way should Applicants invention be limited to closed, "**consisting of**" claim language.

The fact that Applicant's generic claims could encompass various polynucleotide elements which are not recited in the claims is irrelevant as to whether Applicants are entitled to the present claims. What is relevant is whether the present claims, as properly interpreted, meet the statutory requirements for written description under 35 U.S.C. § 112. Applicant believe that all the claims meet these statutory requirements and that the rejections are based on an improper application of the law and should be withdrawn.

The present claims encompass an isolated polynucleotide molecule which is a uroplakin II (UPII) transcriptional response element as set forth in SEQ ID NO:1 or SEQ ID NO:2, and

adenovirus vectors comprising the same. The subject polynucleotide molecules are claimed using an "open" claim structure and thus may include flanking sequences.

The claims do not require any particular flanking sequence or additional TRE, although specific adenovirus coding sequences are recited in some claims. The claimed polynucleotides are demonstrated to have utility as tissue specific enhancers. As such, every one of the claimed polynucleotides has an acknowledged specific, substantial and credible utility. None of these uses requires a claimed polynucleotide comprise additional regulatory elements, other than those known and typically used with an enhancer sequence, *e.g.* the insertion of promoter elements, and coding sequence, as known in the art and demonstrated by Applicants. Given that the claims provide both structural and functional language relative to the UPII TREs encompassed by the claims, Applicants submit that the claim language is consistent in scope with the description provided in the specification, and does not extend beyond the human UPII sequences that are claimed. "Ourcase law is clear that an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention." *Rexnord Corporation v. Laitram Corporation*, 274 F.3d 1336, 1344, 60 U.S.P.Q.2d (BNA) 1851, 1856 (Fed. Cir. 2001). See also *In re Hogan and Banks*, 559 F.2d 595, 605-06, 194 U.S.P.Q. (BNA) 527, 537 (C.C.P.A. 1977); *United States Steel Corporation v. Phillips Petroleum Company*, 865 F.2d 1247, 1251-52, 9 U.S.P.Q.2d (BNA) 1461, 1465 (Fed. Cir. 1989). It is irrelevant whether a later-discovered regulatory element could be used in combination with the recited TRE sequences of the invention. There is simply no basis in the law for the proposition that a genus which is adequately described in a specification as of the filing date nevertheless fails to meet the written description requirement because it could potentially be encompassed within a later discovered molecule.

The U.S. Patent and Trademark Office routinely issues patents that claim DNA molecules encoding full-length genes using open language, as indicated by numerous issued patents. The Office should not find anything *per se* objectionable about open-ended nucleic acid claims, regardless of whether the claim-recited nucleic acid is a regulatory element, or a coding sequence. There is no reasonable basis under the guise of the written description requirement or any other portion of the patent laws for allowing open-ended claims if the recited sequence is "full-length" while denying open-ended claims solely because the claims are defined by a recited sequence that does not encode a full length gene.

There is good reason for allowing open-ended claims to useful polynucleotide molecules like those discovered by Applicant. In the recombinant nucleic acid field, making and using specific polynucleotide molecules routinely involves incorporating the specific polynucleotides into larger molecules, including cloning and expression vectors. Specific polynucleotide molecules retain their

essential utility when linked to additional sequences. Obviously, the variety of useful larger molecules comprising a specific polynucleotide sequence is essentially limitless. In the recombinant DNA field, the practical reality is that larger polynucleotide molecules into which the inventive polynucleotide molecule can be inserted should be viewed simply as the functional milieu in which an inventive sequence can be made and used. In this context, inventors of polynucleotides would be deprived of meaningful patent protection if claims were limited by closed language to the inventive polynucleotide or to specific larger molecules into which Applicant actually incorporated the inventive polynucleotide molecule. Others could use the inventions but avoid the claims easily merely by using the inventive sequences in unclaimed larger molecules. Closed claims for nucleic acids would utterly eviscerate patent protection for those inventions.

Open claims to inventive nucleic acid sequences are analogous to open claims in other fields. For example, claims are routinely allowed that encompass all pharmaceutical formulations of an inventive pharmaceutical without any limitation on the type of pharmaceutical formulation. Where the invention is in the agent, there is no justification for restricting the type of formulation in which the agent could be included, even though such claims would read on future discovered formulations that contain the agent, and even where all possible formulations are not described in the application

The clear rationale for permitting applicants to claim pharmaceutical formulations comprising patentable agents using open-ended language is that requiring any claim limitation on a collateral feature (such as the specific formulation) would allow competitors to use the invention simply by altering a nonessential collateral feature. The law does not limit the inventor of a new pharmaceutical agent to claims covering only the agent itself or the specific formulations the inventor actually made.

In other words, there is no way for Applicant to obtain claims commensurate with Applicant' invention of new and useful sequences other than to claim nucleic acid molecules comprising those sequences. Closed claims like those that would overcome the rejection would be no more useful or fair than a claim to "a device consisting of [an inventive valve]" that could not be enforced against a manufacturer or user of a larger device comprising the valve or a claim to a "new pharmaceutical

agent" that could not be enforced against a manufacturer who incorporated the agent into a formulation for administration.[1]

These concerns apply unequivocally to Applicant' claims. The closed claims offered by the Examiner would not provide Applicant with patent protection commensurate with their invention. The record shows that Applicants specifically teach, and the skilled worker was well aware, that the inventive sequences should be incorporated into larger molecules to make and use them. The record shows that closed claims would deprive Applicant of patent protection on polynucleotides that are fully described in the specification. A polynucleotide containing an addition of a few nucleotide bases or even a single nucleotide base to the end of the recited polynucleotide sequence would retain the utility of the disclosed molecules and yet be outside of the scope of such closed-ended claims. In short, denying Applicant the open-ended claims would permit anyone to avoid Applicant' claims while taking full advantage of Applicant' contribution to the art.

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1 Not only does the law provide no justification for imposing unique patentability requirements on inventions of useful nucleic acid sequences, the law actually proscribes any such differential treatment. Article 27.1 of the TRIPS Agreement states in part that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakech Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 81 (1994). If the United States, through TRIPS, forces the rest of the world to comply with western-style intellectual property norms, we ourselves should not treat any particular technology differently than all other technologies. The uniquely heightened written description standard that the U.S. Patent and Trademark Office seems to be applying to nucleic acid inventions in this case would violate this portion of Article 27.1.

CONCLUSION

Applicants submit that all of the claims are now in condition for allowance, which action is requested. If the Examiner finds that a Telephone Conference would expedite the prosecution of this application, she is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any other fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number CELL-016.

Respectfully submitted,

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